



ORIGINAL ARTICLE

SINGLE WORKING INSTRUMENT, DOUBLE TROCARS, CLIPLESS CHOLECYSTECTOMY USING HARMONIC SCALPEL. A FEASIBLE, SAFE, AND LESS INVASIVE TECHNIQUE

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Abstract

Aim: To evaluate safety and efficacy of harmonic scalpel in closure/division of the cystic duct and artery, and bladder dissection in laparoscopic cholecystectomy as a single working instrument, with the use of two working trocars technique, compared with clip/cautery, three trocars technique.

Method: A prospective study included 160 patients with symptomatic gall stone disease were randomly assigned for laparoscopic cholecystectomy by either harmonic shear, with two trocars (Group I = 80 patients), or Group II (clip/cautery, 3 trocars) including 80 patients.

Results: No significant complications were encountered in either group; however 1 case of Group II suffered mild leakage treated conservatively. Intra-operative bile spillage was insignificantly lower in Group I (10% vs. 13%; $P=0.46$). The median operative time was significantly shorter in Group I (20 vs. 45 minutes; $P=0.0001$). Also hospital stay was significantly shorter in Group I (1 vs. 1.5 days; $P=0.001$), but no significant difference found in the incidence of post-operative complications. The overall cosmetic results and patient satisfaction was better in Group I.

Conclusion: Harmonic shear is as safe and effective as clip/cautery technique in achieving hemo-biliary stasis; with shorter operative time, especially if used solely as a working instrument. Two trocars technique is safe, feasible, and provides better cosmetic results and patient satisfaction.

Keywords: Ultrasonic dissectors, laparoscopic trocars, cosmesis.

INTRODUCTION

Laparoscopic cholecystectomy is a commonly performed operation for patients diagnosed with gall stones. Usually the procedure involves electro surgery, and sealing of the gall bladder duct and arteries with titanium clips. Dissection with concomitant hemostasis can be performed with the use of ultrasonic instruments, such as harmonic scalpel which can radically simplify the whole operation and offer good hemostasis,⁽¹⁾ so ultrasonically activated devices have

been used for dissection with encouraging results.⁽²⁾

The ultrasonically activated (Harmonic) scalpel has proven to be an effective, efficient, and safe instrument for dissection and hemostasis. It works on the tissue's cutting and coagulating very effectively with the replacement of high frequency current, which can be connected with diverse complications. The primary use of the Harmonic scalpel in laparoscopic cholecystectomy has been for the division of the cystic

artery and liver bed dissection.⁽¹⁾ Recently, ultrasonic energy has been used to seal the cystic duct during successful clip-less cholecystectomy.⁽³⁾ So total Harmonic scalpel dissection in the performance of a laparoscopic cholecystectomy was described.⁽⁴⁾

The resulting decrease in temperature, smoke, and lateral tissue damage placed the Harmonic scalpel in contrast to the effects seen with the more traditional electrocautery. In addition, the elimination of inadvertent, sometimes unrecognized, electrical arcing injuries with their potentially hazardous sequelae supported the role of the Harmonic scalpel as a potentially safer instrument for tissue dissection.⁽¹⁾ It tackles the concerns regarding smoke production, and inadvertent injuries to the abdominal organs and structures.⁽⁵⁾ Moreover, it shortens the operative time and decreases the rate of accidental bile spillage.⁽⁶⁾

A single working instrument means avoidance of repeated instrument changes during the operation, as selecting different instruments breaks the natural flow of the operation and may distract the surgeon.⁽⁵⁾

Moreover, downsizing the port incisions may reduce pain after laparoscopic cholecystectomy,⁽⁷⁾ and minimizing the number and scope of ports to improve post-operative pain control, rapid return to activity and work, patient satisfaction, and cosmetic result achieved by the laparoscopic method.⁽⁸⁾ Thus, new techniques for laparoscopic cholecystectomy were designed to reduce the number of trocars, or the use of very thin instruments with the goal of further minimizing surgical invasiveness.⁽⁹⁻¹¹⁾ Some authors use one 1-mm Kirschner wire, introduced at the sub costal line and bent with a special designed device to hook the gallbladder and pull it up,⁽¹²⁾ while others used 2-mm grasper forceps inserted directly without a trocar below the costal margin, then the fundus of the gallbladder is ligated and lifted up with a folded 0 silk string and a 16-gauge vessel cannula.⁽⁹⁾ These feasible, safe, minimal invasive techniques result in a much smaller wound with less pain than conventional laparoscopic cholecystectomy, and considered as an alternative way to deal with gallstone disease, especially for younger women, who tend to be more concerned about cosmetic outcome.⁽¹³⁾

This study was undertaken to demonstrate the efficiency, and safety of the Harmonic scalpel as the sole instrument to achieve complete hemo-biliary stasis in the performance of laparoscopic cholecystectomy, with the use of two trocars technique.

PATIENTS AND METHODS

Patient population: From Jan. 2008 to July 2009, a sample of 160 cases of symptomatic gall stones were included in this study from Unit C, General Surgery Department, Assuit University Hospitals.

Clinical and diagnostic work-up: all patients were

subjected to:

1. Full history taking.
2. Clinical examination.
3. Investigations which included:
 - Routine lab tests (blood count, random sugar, serum creatinine)
 - Routine chest X-ray, ECG, ...etc.
 - Liver function tests.
 - Prothrombine time.
 - Abdominal ultrasonography.
 - Additional investigations were needed sometimes in some doubtful cases as CT, and MRCP.

Management: All patients were randomly assigned for laparoscopic cholecystectomy as follows:

Group I (clip-less Harmonic group) included 80 cases; the Harmonic scalpel was used as a single working instrument with only two working trocars.

Each patient was positioned in an anti-Trendelenburge position with some rotation to the left side to help in good visualization and manipulation of the gall bladder, if difficulty is still encountered, thereafter a curved Kirschner wire 1 mm is introduced in the sub costal area and hooks the gall bladder fundus with gentle retraction upwards, or by direct introduction of the laparoscopic trocars wound closure forceps through the sub costal region with gentle retraction of the gall bladder upwards, however these maneuvers were rarely resolved to during work.

Ultrasonic shear (Olympus Keymed Sono surg version G2 220-240 V 3A. 50/60 Hz.) was used as the only working instrument during the procedure through 10 mm epigastric port, for dissection/cutting of cystic artery and duct, then gall bladder dissection from liver bed helped by grasper through right mid clavicular 5 mm port to attain complete hemo-biliary stasis, lastly the gall bladder is retrieved from the epigastric 10 mm trocars site.

Group II (clip/cautery group) included 80 cases; the conventional instruments were used with the application of clips and the use of the cautery in a three working trocars laparoscopic cholecystectomy technique.

One small catheter drain was put in all cases that was removed a few hours later, All patients were followed up in General Surgery Department, Assuit University Hospitals with post operative treatment in the form of broad spectrum antibiotic prophylaxis, and analgesia according to the amplitude of pain using "pain scoring system" with single shot of narcotics for moderate pain, and double that dose was needed with severe pain (14)

till discharged from hospital.

Recording of all patients data were done, and categorized as: intra-operative difficulty, intra-operative perforation of the bladder and biliary spillage, intra-operative injuries, or complications, operative time, as well as post-operative complications, post-operative pain and the need for analgesics, and hospital stay.

Follow up: patients were followed up in the outpatient clinic for 6 months post-operatively for detection of any complications, and abdominal ultrasonography was additionally done in a week and month intervals post-operatively.

Assessment of the cosmetic results, and consequently patient satisfaction of the surgery was also done by comparison between the resulting scar and conventional post laparoscopic cholecystectomy scar, in addition to other factors as shorter hospital stay, rapid return to normal activity, rapid return to work, and nearly pain free smooth post-operative period in comparison to the other Group studied.

Ethical considerations and informed consent: The study protocol was approved by the local Ethical Committee, and it was explained to each patient and his/her informed consent obtained prior to entry into the study.

Statistical analysis: The results are expressed as the mean \pm SD & number(%). Statistical analysis was performed with the software SPSS Version 12, using student T. test to determine significant numeric data, using Chi Square to determine signs for non- parametric data. P value was determined as significant ($P < 0.05$).

RESULTS

Age and sex incidence in both groups: This study included 160 cases, most of them were females (100 = 62.5%) compared to males (60 = 37.5%), with male to female ratio about 1: 1.6. All data about age groups are shown in Table 1.

Duration of surgery: The surgical maneuver time was statistically significant shorter in harmonic group compared to the regular laparoscopy group as shown in Table 2.

Table 1. Showed age and sex incidence.

| Group► | Group I | | Group II | | Total | |
|------------|---------|---------|----------|---------|-------|---------|
| | Males | Females | Males | Females | Males | Females |
| <20 Years | 2 | 3 | 2 | 2 | 4 | 5 |
| 20-30 | 8 | 17 | 4 | 8 | 12 | 25 |
| 30-40 | 7 | 20 | 6 | 9 | 13 | 29 |
| 40-50 | 6 | 7 | 14 | 18 | 20 | 25 |
| 50-60 | 4 | 5 | 5 | 9 | 9 | 14 |
| >60 Years | - | 1 | 2 | 1 | 2 | 2 |
| Total | 27 | 53 | 33 | 47 | 60 | 100 |
| Percentage | 16.9 | 33.1 | 20.6 | 29.4 | 37.5 | 62.5 |

Table 2. Showed duration of the operation.

| Groups► and duration▼ | Groups | | P. Value |
|--------------------------|------------|--------------|--------------------|
| | Group I | Group II | |
| Range | 9-30 | 35-55 | |
| (minutes) | | | 0.0001 |
| Mean | 20 | 45 | Highly significant |
| (minutes ± SD) | (16.8±6.8) | (44.01±6.47) | |

(N.B Time recorded is the actual surgical interference time without trocar application stitches closure or dressing).

Division of the cystic duct by harmonic scalpel required approximately 2-3 minutes depending on the ductal thickness and associated inflammation. In general the cavitation effect on the surrounding peri-cholecystic tissues especially in the region of the liver bed allowed for easier mobilization of the gall bladder thus avoiding inadvertent compromise of the gall bladder wall and bile spillage. No liver bed charring or bilious seepage from any ducts of Luschka was observed (Figs. 1-6).

Intra-operative complications: There was no statistically significant difference between the two groups as regard the incidence of intra operative complications, however there was a comparable

incidence of intra operative bile spillage (10% vs. 13% for harmonic and regular laparoscopy groups respectively) due to gall bladder perforation or leakage from its duct with manipulation in acute cholecystitis and obstructed distended bladder.

Also difficult maneuver was seen in both groups in comparable incidence, due to distended obstructed bladder in harmonic group (managed by repeated change in patient position), or acute cholecystitis in regular laparoscopy group managed by meticulous maneuvers. Fortunately no conversion to open cholecystectomy encountered as shown in Table 3.

Post operative complications: There was only one case of post operative bile soaking that was treated conservatively in the regular laparoscopy group. The post operative pain was somewhat more in regular laparoscopy group and consequently more dose of analgesic was needed than harmonic group as shown in Table 4.

Hospital stay: The hospital stay was statistically significant shorter in the harmonic group than regular laparoscopy group as shown in Table 5.

Follow up: All patients were followed up in the general surgery department till discharge for outpatient clinic follow up with meticulous monitoring of their satisfaction about the surgical maneuver and the cosmetic results that was in favor of the harmonic group more than the regular laparoscopy group.

Table 3. Showed intra operative complications.

| The complication | Group I | | Group II | | P Value |
|----------------------|---------|-----|----------|-----|-----------------|
| | No. | % | No. | % | |
| Bile spillage | 8 | 10 | 11 | 13 | 0.46 |
| Biliary injury | - | - | - | - | Not significant |
| Bleeding | - | - | 1 | 1.3 | - |
| Difficult to proceed | 1 | 1.3 | 1 | 1.3 | - |
| Conversion to open | - | - | - | - | - |

Table 4. Showed post operative complications.

| Item | Group I | | Group II | |
|----------------------|----------|-----|----------|---|
| | No. | % | No. | % |
| Biliary soaking | 1 | 1.3 | - | - |
| Biliary injury | - | - | - | - |
| Abdominal collection | - | - | - | - |
| Post-operative pain | moderate | | Severe | |
| Analgesics doses | Single | | Double | |
| Post-operative ileus | - | - | - | - |

N.B Assessmet of pain and consequently narcotics prescribed by "pain scoring system" (Melzack R, and Katz J: Pain measurement in person in pain. In: Textbook of pain, R.Wall, R. Melzack (eds), 1999).

DISCUSSION

Cholecystectomy is a commonly performed operation for patients with symptomatic gall stone disease.⁽⁵⁾ Laparoscopic cholecystectomy today is the standard operation, and it has given new impulses to the surgery of the gall bladder and has proven to be an effective, patient-friendly alternative to open surgery.^(15,16)

Two working trocars technique: Many important advantages of laparoscopic surgery are produced by preservation of the integrity of abdominal wall, including less operative trauma and complications, better recovery and good cosmetic results.⁽¹⁰⁾ Several attempts have been made to reduce operative trauma further by decreasing the number and size of the trocars, the use of three trocars instead of four, and the use of mini-instruments, is definitely a step in this direction.^(17,18)

In this study, two working trocars were used in harmonic clipless group instead of three working

trocars in the other group, consequently the harmonic two working trocars group had better cosmetic results and more patient satisfaction in follow up, In agreement with the worldwide attention of minimal invasiveness looking to further reduction of the operative trauma, preservation of the integrity of abdominal wall, with better recovery, and improved cosmetic results.^(9,10) The use of two working trocars instead of three is definitely a step in this direction,⁽¹¹⁾ with improvement of post operative pain, return to activity and work, and better patient satisfaction.⁽⁸⁾

Single working instrument: In this study, the harmonic scalpel was used as a single working instrumen, not only to document the efficiency of single working instrument, but also to evaluate its use in dissection and achieving hemo-biliary stasis. As agreed by Nicholas Marshall that a single instrument means avoidance of repeated instrument changes during the procedure, and selecting different instruments breaks the natural flow of the operation and may distract the surgeon.⁽⁵⁾

Table 5. Showed periods of hospital stay.

| The item | Group I | Group II | P. Value |
|-------------------------------|---------------|---------------|-------------|
| Range of hospital stay period | 1 | 1-2 | |
| Mean duration of | 1 | 1.5 | 0.001 |
| hospital stay (± SD) | (1.00 ± 0.00) | (1.53 ± 0.51) | Significant |



Fig 1. Harmonic scalpel and two working trocars.

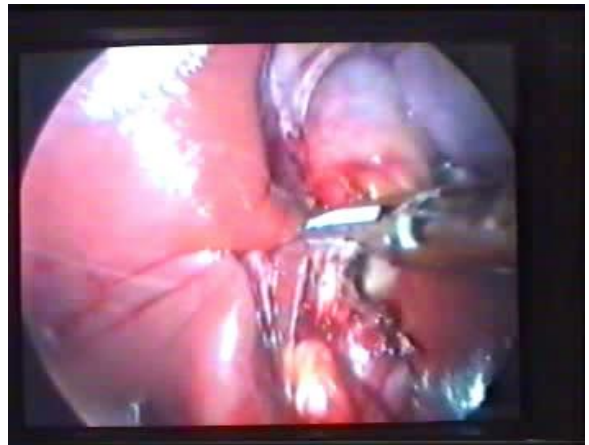


Fig 4. Lap. harmonic coagulation/cutting of the cystic duct.

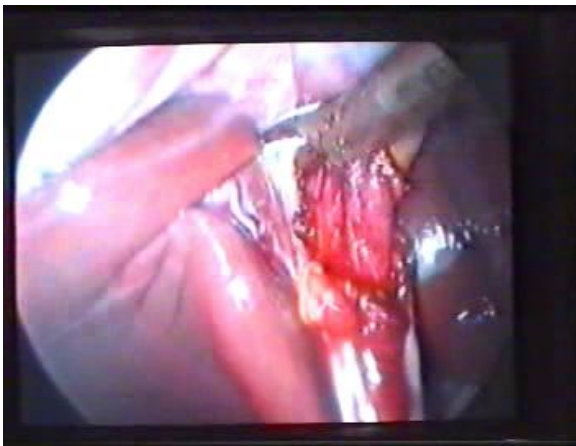


Fig 2. Lap. anterior and posterior dissection of cystic artery.

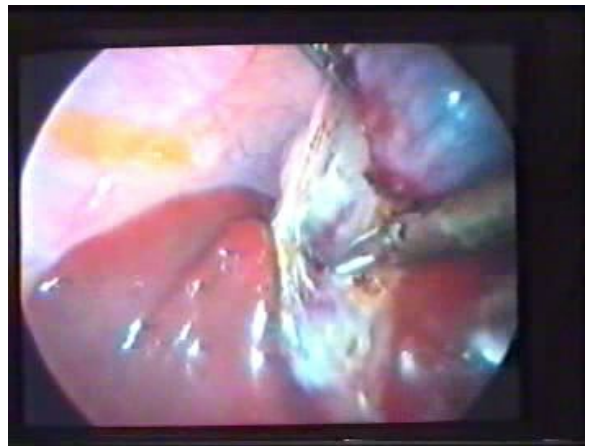


Fig 5. Lap. dissection of gall bladder from the liver, with bed hemo-biliary stasis.

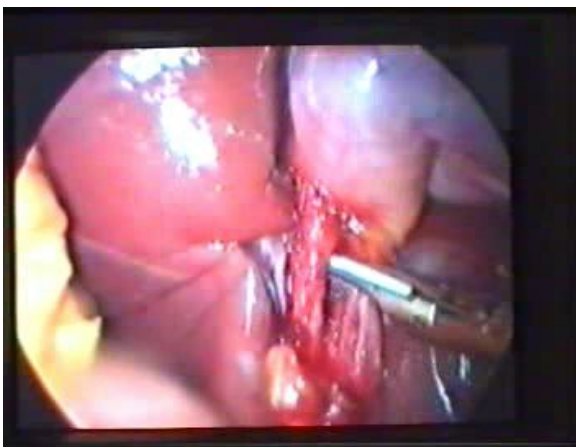


Fig 3. Lap. harmonic coagulation/cutting of the cystic artery.



Fig 6. Immediate post operative view of the abdomen.

Harmonic scalpel uses: This study clearly demonstrates that the harmonic scalpel provides complete and reliable hemo-biliary stasis without clinically significant immediate or remote post operative complications.⁽¹⁹⁾ It was feasible, easily handled, and very efficient.

Except for the 2-3 minute interval required for cystic duct division, the use of harmonic scalpel did not adversely affect the length of the procedure; more over it significantly shorten the operation time (20 vs. 45 minutes respectively for harmonic and regular laparoscopy with P value = 0.0001). In fact the properties intrinsic to the harmonic scalpel (cavitations and smokeless coagulation) seem to provide an advantage over electrocautery in the dissection of the gall bladder and may enhance surgeon performance,^(1,6,19) in agreement with other authors that its application shortens operative time.⁽⁸⁾ Moreover harmonic scalpel division of the cystic duct could be utilized independently of the direction of the gall bladder dissection with effective hemo-biliary stasis.⁽¹⁾

Intra operative bile spillage was slightly less encountered in harmonic group than regular clip/cautery group (10% vs. 13% respectively with P value = 0.46) with no intra operative blood soaking in comparison to one case belongs to regular laparoscopy group, and this may be attributed to the effectiveness of harmonic scalpel in gall bladder dissection with hemo-biliary stasis, with efficient closure of the Duct of Luschka. The small incidence of bile spillage encountered in harmonic group was not due to gall bladder perforation but attributed to the early experience with the device without efficient closure of the cystic duct; hence it is seen only in initial cases. Most authors denotes that harmonic clip less cholecystectomy is associated with significantly lower incidence of gall bladder perforation and bile spillage.^(2,3,19)

Post operative complications: One patient suffers from post operative bile leakage belonged to regular laparoscopy group and treated conservatively, but no major post operative complications or injuries encountered in either group. This proved the effectiveness of harmonic scalpel that prevents post operative bile leakage from the liver bed that may contribute to post operative pain, small bilomas, and the associated return to the operative room as documented by Nazih and others;^(1,2,6,19,20) hence patients in harmonic group suffers less post operative pain, with the need of single dose of analgesics post operatively in comparison to regular laparoscopy group whom needed double that dose.

Hospital stay: In this study, hospital stay was statistically significant lower in harmonic group than regular clip/cautery group (1 vs. 1.5 days respectively with P value = 0.001), in agreement with data documented by other authors that harmonic scalpel clipless cholecystectomy decreases hospital stay period.^(1,5,19) In spite Tsimoyiannis et al⁽²¹⁾ demonstrated

comparable recovery times, but Subjective observations throughout this study does not substantiate this finding.

In conclusion The Harmonic scalpel is a safe, efficient, and practical instrument to use during laparoscopic cholecystectomy especially if used as a sole working instrument, with complete hemo biliary stasis. Its application shortens the operative time and decreases accidental bile spillage; hence decreases postoperative complications, with shorter hospitalization period.

Downsizing the number or size of laparoscopy trocars improved the results of minimal invasiveness with better recovery, less pain, improved cosmesis, and better satisfaction.

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